

**Generic Name:** Mepolizumab

**Therapeutic Class or Brand Name:** Nucala®

**Applicable Drugs (if Therapeutic Class):** N/A

**GPI Code:** 4460405500

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 2/5/2016

**Date Last Reviewed / Revised:** 8/14/2020

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I and II are met)

- I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:
  - A. Severe asthma with eosinophilic phenotype AND criteria 1 through 4 are met:
    1. Documented blood eosinophilia count of at least 150 cells/mcL in the previous 6 weeks.
    2. Documentation that patient has been on a minimum of a six-month trial of a high-dose inhaled corticosteroid (ICS) used in combination with a long-acting inhaled beta-2 agonist AND both criteria a and b are met:
      - a) Documentation that patient is adherent to therapy as evidenced by pharmacy claims review (patient must have MPR greater than or equal to 80% over the previous 180 days).
      - b) Documentation that patient's asthma symptoms are poorly controlled despite therapy.
    3. Documentation that environmental factors and comorbid conditions that worsen patient's asthma symptoms are being identified and resolved.
    4. Minimum age requirement: 6 years old.
  - B. Eosinophilic granulomatosis with polyangiitis (EGPA) affecting pulmonary system AND criteria 1 and 2 are met:
    1. Documentation that patient has at least 4 of the following criteria a through f:
      - a) Asthma.
      - b) Eosinophilia greater than 10% on differential white blood cell count.
      - c) Mononeuropathy (including multiplex) or polyneuropathy.
      - d) Non-fixed pulmonary infiltrates on roentgenography.
  - C. Eosinophilic granulomatosis with polyangiitis (EGPA) and 1-4 are met
    1. Documentation that the patient has:

- a) Asthma
  - b) Blood eosinophils  $\geq 1500$  cells/mL and/or  $\geq 10$  percent of leukocytes
  - c) Systemic vasculitis involving two or more extra-pulmonary organs
2. Documentation that patient is stable on daily corticosteroid therapy or has a contraindication to corticosteroid therapy.
  3. Documented trial and failure of, intolerance to, or contraindication to at least one other immunosuppressant (i. e. azathioprine, cyclophosphamide, methotrexate).
  4. Minimum age requirement: 18 years old.
- II. Prescriber must be an allergist, immunologist, pulmonologist, or rheumatologist.

## EXCLUSION CRITERIA

- Concurrent use with other anti-asthma monoclonal antibodies (i.e. Cinqair® (reslizumab), Fasentra™ (benralizumab), Xolair® (omalizumab), Dupixent® (dupilumab)).
- Treatment of other eosinophilic conditions.
- Treatment of acute bronchospasm or status asthmaticus.

## OTHER CRITERIA

- N/A

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- Severe eosinophilic asthma 6-11 years: 40 mg every 28 days.
- Severe eosinophilic asthma 12 years and older: 100 mg every 28 days, either by vial or prefilled autoinjector.
- EGPA: 300 mg every 28 days.

## APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

## APPENDIX

N/A

## REFERENCES

1. [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Nucala/pdf/NUCALA-PI-PIL.PDF](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Nucala/pdf/NUCALA-PI-PIL.PDF).
2. <http://www.nhlbi.nih.gov/files/docs/guidelines/asthgdln.pdf>.
3. <http://onlinelibrary.wiley.com/doi/10.1002/art.1780330806/pdf>.
4. [http://www.ejinme.com/article/S0953-6205\(15\)00144-2/fulltext](http://www.ejinme.com/article/S0953-6205(15)00144-2/fulltext).
5. [Medi-Span](#).
6. [https://www.uptodate-com.libproxy.unm.edu/contents/clinical-features-and-diagnosis-of-eosinophilic-granulomatosis-with-polyangiitis-churg-strauss?search=eosinophilic%20granulamatois&topicRef=100544&source=related\\_link](https://www.uptodate-com.libproxy.unm.edu/contents/clinical-features-and-diagnosis-of-eosinophilic-granulomatosis-with-polyangiitis-churg-strauss?search=eosinophilic%20granulamatois&topicRef=100544&source=related_link)

**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.